

CLAIMS

What we claim is:

1. An isolated and purified nucleic acid molecule having a nucleotide sequence selected from the group consisting of:

(a) a nucleotide sequence set forth in Figure 3, 4 or 5 (SEQ ID Nos: 5, 6, 8, 9, 11, 12) for *Moraxella catarrhalis* strains 4223, Q8 and LES-1 respectively or the complementary sequence thereto,

(b) a nucleotide sequence encoding an about 200 kDa outer membrane protein of a strain of *Moraxella catarrhalis* and having the derived amino acid sequence shown in Figures 3, 4 or 5 (SEQ ID Nos: 7, 10, 13) for *Moraxella catarrhalis* strains 4223, Q8 and LES-1 respectively, and

(c) a nucleotide sequence encoding an about 200 kDa outer membrane protein of another strain of *Moraxella catarrhalis* which is characterized by a tract of consecutive G nucleotides which is 3 or a multiple thereof in length, an ATG start codon about 80 to 90 bp upstream of said tract and said tract being located between about amino acids 25 and 35 encoded by the nucleotide sequence.

2. The nucleic acid molecule of claim 1 wherein said another strain of *Moraxella catarrhalis* in (c) is a strain as identified in Table 1A other than strains 4223, Q8 and LES-1 and expressing an about 200 kDa protein.

3. An isolated and purified nucleic acid molecule having a nucleotide sequence selected from the group consisting of:

(a) a nucleotide sequence set forth in Figure 8 (SEQ ID No: 12) for a 5'-truncation of the gene encoding an about 200 kDa outer membrane protein of *Moraxella catarrhalis* strain 4223.

Sub
B'

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Sub
B'

Sub
C8

(b) a nucleotide sequence encoding the derived amino acid sequence set forth in Figure 9 (SEQ ID No: 13) for a N-terminal truncation of an about 200 kDa outer membrane protein of *Moraxella catarrhalis* strain 4223, and

(c) a nucleotide sequence encoding a 5'-truncation of a gene encoding an about 200 kDa outer membrane protein of another strain of *Moraxella catarrhalis* and being capable of expressing the corresponding N-terminally truncated about 200 kDa outer membrane protein from *E. coli*.

4. An isolated and purified nucleic acid molecule which is a contiguous Nde I - Pst I fragment of SEQ ID No: 5.

5. A vector for transforming a host comprising a nucleic acid molecule as claimed in any one of claims 1 to 4.

6. The vector of claim 5 which is a plasmid vector.

7. The vector of claim 5 which has the identifying characteristics of pKS348 (ATCC 203529) shown in Figure 10 or pKS294 (ATCC 203528) shown in Figure 9.

8. The vector of claim 5 which has the identifying characteristic of pQWE shown in Figure 19 or pQWE shown in Figure 20.

9. A host cell transformed by a vector as claimed in claim 5 and expressing an about 200 kDa protein of a strain of *Moraxella catarrhalis* or an approximately C-terminal half thereof.

10. The host cell of claim 9 which is *E. coli*.

11. A recombinant about 200 kDa outer membrane protein of a strain of *Moraxella catarrhalis* or an approximately C-terminal half thereof producible by the transformed host of claim 9.

12. The recombinant protein of claim 11 producible in inclusion bodies.

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Sub D3

503

ET

7 SEQ 12 20/10/96
Nucleic Acid
4223

→ encodes
full length
200000
4223

Plasmid
C term 200000
N term 4223

plasmid

C term 200000
or 200000

13. An immunogenic composition comprising the recombinant about 200 kDa outer membrane protein or an approximately C-terminal half thereof of claim 11.
14. The immunogenic composition of claim 13 formulated as a vaccine for *in vivo* administration to protect against disease caused by *Moraxella catarrhalis*.
15. The immunogenic composition of claim 13 in combination with a targeting molecule for delivery to specific cells of the immune system or to mucosal surfaces.
16. The immunogenic composition of claim 13 formulated as a microparticle, capsule or liposome preparation.
17. The immunogenic composition of claim 13 further comprising an adjuvant.
18. A method of inducing protection against disease caused by *Moraxella catarrhalis*, comprising administering to a susceptible host an effective amount of the immunogenic composition of claim 13.
19. The method of claim 18 wherein said susceptible host is a human.
20. A method for the production of an about 200 kDa outer membrane protein of a strain of *Moraxella catarrhalis* or an approximately C-terminal half thereof, which comprises:
- transforming a host with a vector as claimed in claim 5,
 - growing the host cell to express the encoded about 200 kDa protein or an approximately C-terminal half thereof, and
 - isolating and purifying the expressed about 200 kDa protein or an approximately C-terminal half thereof.
21. The method of claim 20 wherein the host cell is *E. coli*.
22. The method of claim 20 wherein said encoded about 200 kDa protein is expressed in inclusion bodies.

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23. The method of claim 22 wherein said isolation and purification of the expressed about 200 kDa protein is effected by:

disrupting the grown transformed cells to produce a supernatant and the inclusion bodies,

solubilizing the inclusion bodies to produce a solution of the recombinant about 200 kDa protein,

chromatographically purifying the solution of recombinant about 200 kDa protein free from contaminating proteins, and

isolating the purified recombinant about 200 kDa protein.

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